MAY 13 2011

Exhibit #1 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K102328

1. Date of Submission: 03 MAY 2011

2. Sponsor
   ShanDong WeiGao Group Medical Polymer Co., Ltd
   No. 348, Shichang Road, Weihai
   Shandong, 264209, China
   Establishment Registration Number: 3007084575
   Contact Person:
   Ms. Suxia Zhao, Quality Manager
   T: +86-631-5621632
   F: +86-631-5620555
   E: zsx9001@sina.com

3. Submission Correspondent
   Ms. Diana Hong / Mr. Lee Fu
   Shanghai Mid-Link Business Consulting Co., Ltd
   P.O. BOX 237-023
   Shanghai, 200237, China
   T: +86-21-22815850
   F: 240-238-7587
   E: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Blunts
   Proposed Device Model: Blunt Fill Needle and Blunt Plastic Cannula
   Regulation Name: needle, hypodermic, single lumen
   Classification: Class II
   Product Code: FMI
   Regulation Number: 21 CFR 880.5570

5. Intended Use

The blunts include two models, which are blunt fill needle and blunt plastic cannula.

The blunt fill needle is used in conjunction with a syringe to penetrate the vial/ampoules stopper intended for injection or aspiration of fluid.

The blunt plastic cannula is used in conjunction with a syringe to access the pre-slit septum covering injection sites on I.V. System intended for injection or aspiration of fluid.

6. Predicate Device Identification

510(k) Number: K974006
Product Name: BD TwinPak
Manufacturer: Becton and Dickinson Company

7. Device Description

The blunts include two models, which are blunt fill needle and blunt plastic cannula. The blunt fill needle is an 18G stainless needle tube with a luer slip hub. It is used to penetrate the vial and/or ampoules stopper intended for injection or drawl fluid. The hub is a luer slip female conical fitting, which can be connected to the luer slip male conical fitting on the syringe. It is not intended to access the injection site on I.V. System. The blunt plastic cannula is a molded plastic blunt tipped cannula to penetrate pre-slit septum injection site on I.V. Safety Systems, which is designed for penetration with needleless I.V. access device, intended for injection and/or aspiration of fluid. It also has a luer slip female conical fitting, which can be connected to the luer slip male conical fitting on the syringe to be filled. The blunt plastic cannula is used to replace hypodermic needles to prevent from the unintended injury by metal needle. These two products can be sold together in one immediate package or respectively in separate immediate packages.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

a) Female Luer Slip Connector of both blunt fill need and blunt plastic cannula were tested per ISO 594-1:1986 to evaluate whether it could be compatible with standard male luer slip connector of the syringe.
b) Blunt Fill Needle was tested per ISO 7864:1993 and ISO9626:1991 to evaluate its physical and chemical specifications.
c) There is no international performance standard established for blunt plastic cannula. The sponsor has performed the testing on surface condition of the blunt plastic cannula, and comparison test between the proposed and predicate device.

9. Substantially Equivalent Analysis and Conclusion

Table 1 Comparison of Technological Characteristic

Item	Proposed Device Blunts	Predicate Device BD TwinPak, K974006
Indications for Use	The blunts include two models, which are blunt fill needle and blunt plastic cannula. The blunt fill needle is used in conjunction with a syringe to penetrate the vial/ampoules stopper intended for injection or aspiration of fluid. The blunt plastic cannula is used in conjunction with a syringe to access the pre-slit septum covering injection sites on I.V. System intended for injection or aspiration of fluid.	Substantially Equivalent
Components	Blunt Fill Needle Blunt Plastic Cannula	Substantially Equivalent
Blunt Fill Needle Gauge	18 G	20 G
Material		
Blunt Fill Needle	Stainless Steel	Substantially Equivalent
Blunt Plastic Cannula	Polycarbonate	Polypropylene
Sterilization		
SAL	10^{-6}	Substantially Equivalent
Method	Radiation	Substantially Equivalent
Biocompatibility	Comply with ISO 10993 Standards	Substantially Equivalent
Safety and Effectiveness	Various performance tests conducted to demonstrate the safety and effectiveness of the proposed device.	Some comparison tests conducted that the proposed device has similar performance with the predicate device.

Compared with the identified predicate device, the proposed device has same indications, component and design features as well as the sterilization requirements. They are different in Needle Gauge of Blunt Fill Needle and Material of Blunt Plastic, but these differences are approved not to affect the safety and effectiveness equivalence between the predicate and proposed device.

The proposed device, Blunts including Blunt Fill Needle and Blunt Plastic Cannula, is determined to be Substantially Equivalent (SE) to the predicate device, BD TwinPak as cleared in K974006, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shandong Weigao Group Medical Polymer Company, Limited
C/O Ms. Diana Hong
Shanghai Mid-Link Business Consultants Company, Limited
P.O Box 237-023
Shanghai, China 200237

MAY 13 2011

Re: K102328
Trade/Device Name: Blunts Model: Blunt Fill Needle and Plastic Cannula
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 3, 2011
Received: May 6, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #2 Indications for Use

510(k) Number: K102328
Device Name: Blunts
Model: Blunt Fill Needle and Blunt Plastic Cannula

Indications for Use:

The blunts include two models, which are blunt fill needle and blunt plastic cannula.

The blunt fill needle is used in conjunction with a syringe to penetrate the vial/ampoules stopper intended for injection or aspiration of fluid.

The blunt plastic cannula is used in conjunction with a syringe to access the pre-slit septum covering injection sites on I.V. System intended for injection or aspiration of fluid.

☒PRESCRIPTION USE	☐OVER-THE-COUNTER USE
(Part 21 CFR 801 Subpart D)	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/10/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102328